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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,306	06/12/2001	Katy Drieu	00537/168002	3283

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BIOMEASURE, INCORPORATED
27 Maple Street
Milford, MA 01757-3650

EXAMINER

JARVIS, WILLIAM R A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,306

Applicant(s)

DRIEU, KATY

Examiner

William R. Jarvis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 12-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,002,965 (Ramwell) for reasons of record.

3. The remarks filed 01 October 2002 regarding the obviousness rejection have been carefully considered, but are not persuasive. The remarks that the prior art does not disclose a therapeutic use of the preferred ginkgolides is not convincing since the use of the compounds in preserving organs in transplantation would be considered by one skilled in the art to be a medical use. Although organ donors are often deceased at the time of transplantation, it is certainly conceivable that the invention could be used by a "live" transplantation (e.g. kidney transplantation from one sibling to another). The remark that the ginkgolide as employed in the invention of the prior art is similar to an embalming fluid rather than a pharmaceutical is not persuasive since embalming fluids are toxic to live tissue and are used merely to retard microbial degradation. Furthermore, the reference also states that it is desirable to administer the ginkgolide to the organ recipient, clearly suggesting a therapeutic use in a live patient; see column 2, lines 9-23.

4. Applicant's interpretation of *In re Hack* is different from examiner's. As explained *supra*, the claimed pharmaceutical compositions of ginkgolides are clearly obvious to one skilled in the art in view of Ramwell and are structurally identical in the methods employed by Ramwell, there being no qualitative or quantitative limitations distinguishing the claimed compositions therefrom. If applicant were to carefully read the previous office action, there is no statement that the composition claimed herein differs from that employed by the prior art, but

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rather the present invention differs in that Ramwell does not exemplify a pharmaceutical composition absent employment for a specific use. *In re Hack* states that it would be appropriate for applicant to claim his invention in the form of method of use claims rather than composition claims. The intended uses of the composition as an inhibitor of membrane expression of a benzodiazepine receptor, an inhibitor of glucocorticoid release, or as an elevator of ACTH levels are given weight in method or process claims, but not in product claims. In addition, see *In re Skoner* 186 USPQ 80 (CCPA 1975); *In re Kalm* 154 USPQ 10 (CCPA 1967); and *In re Halley* 132 USPQ 16 (CCPA 1961).

5. *In re Wiggins* is not appropriate to this fact situation since the compounds of the prior art are **identical** to those of the claimed invention. The pharmaceutically acceptable carriers of the prior art allows for injectable solutions which encompass those of the present invention; see for example column 3, line 66 to column 5, line 33. Neither *In re Baird* nor *In re Vaeck* are applicable to this fact situation since the claimed compounds are not merely encompassed by a disclosed generic formula, but rather the species (i.e. ginkgolides A and B) are taught by the prior art. Clearly, a *prima facie* case of obviousness has been established in the rejection of record. Again, the obviousness rejection is based not on structural similarity, but on identical compounds. A showing of unexpected advantages of the compounds with respect to a particular use may be applicable to method or process claims limited to that use, but does not overcome an obviousness rejection over a product claim directed to identical compounds with no limitations distinguishing carriers or excipients therefrom. Accordingly, the obviousness rejection of record stands.

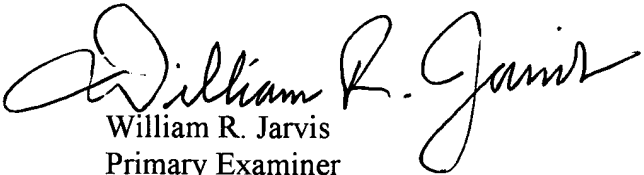
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. Jarvis whose telephone number is 703-308-4613. The examiner can normally be reached on Monday, Tuesday, Thursday & Friday 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne C. Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


William R. Jarvis
Primary Examiner
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wrj
December 18, 2002